

Appl. No. 10/016,632
Response dated August 26, 2004
Reply to Office Action dated June 2, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

- 1 1. (Currently amended) A percutaneous gastrostomy device comprising:
2 a tubular portion defining a longitudinal axis;
3 an internal bolster having a single radial wing secured to said tubular portion,
4 said internal bolster being flexible to permit elastic deformation between a first
5 orientation generally aligned with said longitudinal axis, with the wing wrapped into a
6 generally cylindrical configuration and a second orientation with the wing unfurled and
7 extending generally transverse to said tubular portion longitudinal axis; and
8 a constraining member encasing said internal bolster to retain said internal
9 bolster in said first orientation, with said wing wrapped into said generally cylindrical
10 configuration, and to cover at least a major portion of said wrapped wing, wherein the
11 removal of said constraining member permits the internal bolster to move from said first
12 orientation to said second orientation.

- 1 2. (Original) A percutaneous gastrostomy device comprising:
2 a tubular portion having a distal end;
3 an internal bolster secured to said distal end, said internal bolster having a radial
4 wing secured to said tubular portion, said internal bolster being flexible to permit elastic
5 deformation between a first orientation generally aligned with said longitudinal axis, with
6 the wing wrapped into a generally cylindrical configuration and a second orientation with
7 the wing unfurled and extending generally transverse to said tubular portion longitudinal
8 axis, said wing including a pocket;
9 a rod member, a projecting end and a handle, said rod member having a hollow
10 tube along its longitudinal axis, said rod member being removably received within said
11 tubular portion and said projecting end being removably received within said pocket of
12 said internal bolster; and

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13 a constraining member encasing said internal bolster to retain said internal
14 bolster in said first orientation, with said wing wrapped into said generally cylindrical
15 configuration and to cover at least a major portion of said wrapped wing, said
16 constraining member having a ripcord attached thereto for tearing said constraining
17 member and deploying said internal bolster, allowing said internal bolster to move from
18 said first orientation to said second orientation.

1 3. (Original) The percutaneous gastrostomy device according to claim 1,
2 wherein the constraining member encasing said internal bolster is in the form of a
3 capsule.

1 4. (Previously presented) The percutaneous gastrostomy device according
2 to claim 2, wherein the constraining member encasing said internal bolster is in the form
3 of a capsule having an axial hole therein.

1 5. (Original) The percutaneous gastrostomy device as set forth in claim 4,
2 wherein said ripcord is threaded through the hollow tube, through an opening in a
3 pocket on the internal bolster, through a passage in the pocket, and out through a
4 pocket exit hole, through the capsule, through a hole in the capsule, along the sidewall
5 of the capsule and back through the pocket exit hole and back through the hollow tube,
6 both ends of the ripcord extending through a handle of the rod member and both ends
7 are fastened to a pull tab.

1 6. (Original) The percutaneous gastrostomy device as set forth in claim 5,
2 wherein said ripcord is threaded through said the hole located in said capsule and along
3 a side of a wall of said capsule and positioned to tear said capsule wall.

1 7. (Original) The percutaneous gastrostomy device as set forth in claim 5,
2 wherein said ripcord is threaded twice through said hole located in said capsule and
3 along each side wall of said capsule to tear said capsule walls.

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1 8. (Original) The percutaneous gastrostomy device as set forth in claim
2 3, wherein said capsule is made of a material dissolvable in the patient's stomach.

1 9. (Original) The percutaneous gastrostomy device as set forth in claim
2 4, wherein said capsule is made of a material dissolvable in the patient's stomach.

1 10. (Withdrawn) The percutaneous gastrostomy device according to claim
2 1, wherein the constraining member encasing said internal bolster is in the form of a
3 wrapping.

1 11. (Original) The percutaneous gastrostomy device according to claim 2,
2 wherein the constraining member encasing said internal bolster is in the form of a
3 wrapping.

1 12. (Withdrawn) The percutaneous gastrostomy device as set forth in claim
2 10, wherein said wrapping is made of a material dissolvable in the patient's stomach.

1 13. (Original) The percutaneous gastrostomy device as set forth in claim 11,
2 wherein said wrapping is made of a material dissolvable in the patient's stomach.

1 14. (Withdrawn) The percutaneous gastrostomy device as set forth in claim
2 12, wherein said wrapping is made of a material dissolvable in the patient's stomach at
3 a temperature range of between 50 -100 degree F.

1 15. (Original) The percutaneous gastrostomy device as set forth in claim
2 13, wherein said wrapping is made of a material dissolvable in the patient's stomach at
3 a temperature range of between 50 -100 degree F.

1 16. (Original) The percutaneous gastrostomy device as set forth in claim
2 1, wherein a locking ring is positioned medially along the tubular portion, and sized to

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3 frictionally engage the tubular portion, and slidably mounted there along, and adjustable
4 solely by frictional engagement with the tubular portion to accommodate to the size of
5 the wearer, the locking ring providing a plurality of perforations and spaced ridges to
6 enable air circulation between the locking ring and the body.

1 17. (Original) The percutaneous gastrostomy device as set forth in claim
2, wherein a locking ring is positioned medially along the tubular portion, and sized to
3 frictionally engage the tubular portion, and slidably mounted there along, and adjustable
4 solely by frictional engagement with the tubular portion to accommodate to the size of
5 the wearer, the locking ring providing a plurality of perforations and spaced ridges to
6 enable air circulation between the locking ring and the body.

1 18. (Withdrawn) A method of assembling a percutaneous gastrostomy
2 device comprising the steps of:

3 providing a tube having a longitudinal axis;
4 an internal bolster having a radial wing secured to said tube, said internal bolster
5 being secured to said distal end, said internal bolster having a radial wing secured to
6 said tubular portion, said internal bolster being flexible to permit elastic deformation
7 between a first orientation generally aligned with said longitudinal axis, with the wing
8 wrapped into a generally cylindrical configuration and a second orientation with the wing
9 unfurled and extending generally transverse to said tubular portion longitudinal axis,
10 said bolster having a radially extending pocket formed on an upper surface of said wing;

11 a rod member;
12 a capsule; and

13 providing an assembly fixture comprising a first assembly block having a
14 longitudinal bore extending from one end of said first block and partially therethrough
15 and communicating with a conical passage which converges inwardly from another end
16 of said block;

17 inserting a distal end of said rod into said pocket to flex the pocket in axial
18 alignment with said rod;

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19 providing a second assembly block having a cavity therein adapted to receive
20 said capsule, said second block being adapted to be received in said longitudinal bore;
21 Inserting said capsule into said cavity;
22 inserting said second block into said longitudinal bore;
23 inserting said wing into said capsule by advancing rod into said conical passage
24 to progressively fold the wing over the pocket and the rod to form a folded assembly;
25 and
26 further advancing the folded assembly into the capsule.

1 19. (Withdrawn) A method of installing a percutaneous gastrostomy device
2 within a patient, said device including a tubular portion with a distal end, a folded
3 internal bolster with a radial wing, a constraining member encapsulating said internal
4 bolster, a rod member having a portion that is removable received with a pocket formed
5 in said radial wing, a ripcord extending through said device and having a pull tab outside
6 said device, said rod member and said constraining member cooperating to releasably
7 retain said radial wing in an installation orientation; said method comprising the steps
8 of:

9 positioning said device such that said distal end of said tubular portion is spaced
10 inwardly of an internal surface of the patient;

11 releasing said folded internal bolster to a deployed orientation by employing said
12 pull tab on said ripcord and tearing said constraining member; and

13 removing said rod member projecting end from said pocket on said radial wing
14 to permit said internal bolster to obtain the second orientation with the wing unfurled
15 and extending generally transverse to said tubular portion longitudinal axis.

1 20. (Withdrawn) The method according to claim 19, wherein said rod
2 member is disposed within said tubular portion, comprising the further step of removing
3 said rod from said tubular portion.